TESTIMONY
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Introduction

Good morning. Mr. Chairman and distinguished members of the Subcommittee, I'm pleased to have the opportunity to speak with you today and present to you the Food and Drug Administration's Fiscal Year 2005 budget request. I am Dr. Lester M. Crawford, DVM, Ph.D. Acting Commissioner, Food and Drug Administration.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

I'd like to begin by conveying my appreciation to the Subcommittee members and their staffs for providing FDA with several key increases in the FY 2004 appropriation such

as those funds for generic drugs, food defense, and medical device review. In a moment, I will elaborate on how we have spent or plan to spend those funds in the current year. I can assure you that funds appropriated in the current year and additional increases appropriated in FY 2005 will continue to be spent wisely. As some of my staff like to remind me, the American people would be impressed if they really knew how much bang for their buck they get out of FDA.

FDA is working diligently to reduce administrative and IT costs in FY 04 and 05. In FY04, we offered $57 million in IT and administrative savings and we have again proposed another $23 million in administrative savings in FY05, which we are realizing through efficient administrative resource management. We will continue to seek administrative resource savings in order to support our critical mission requirements. I am fully aware of the difficult funding decisions all of you must face in the current session, but I want to remind you that marginal investments in FDA's programs can have such a positive ripple effect across all of your constituencies – from the consumer to the farmer to the manufacturer and beyond.

Executive Summary

FDA makes substantial and meaningful differences in the lives of over 290 million Americans. I am extremely thankful for the professional dedication, creativity, and expertise of our staff. Through a combination of dedicated staff and their skilled abilities, with the new authorities of recently passed legislation, and the resources this

Subcommittee provides us for carrying out our mission, we will be in a better position to meet our challenges than ever before.

The Administration and Congress have an obligation to the American public to ensure that adequate and properly targeted resources are available for the continued success of the Agency and the success of the Federal Government's efforts to promote quality health care. The importance and complexity of FDA's work will only increase in the years to come as FDA continues to carry out its primary mission of protecting and promoting the public health. This means that while more medical products and therapies will be available to save and improve lives, FDA also must think critically and carefully about how it uses its resources to improve the public wellbeing. In guiding us through our new Strategic Action Plan that attempts to balance demands with limited resources, we will constantly follow the practice of "efficient risk management."

FDA's Strategic Plan

On August 20, 2003, FDA released a 5-Part Strategic Action Plan entitled "Protecting and Advancing America's Health: A Strategic Action Plan for the 21st Century." This is a dynamic and evolving document that outlines how the Agency is taking new steps to protect and advance America's public health. In response to various public health threats, the Agency developed a core set of consumer-focused goals that includes the following: helping consumers get truthful and non-misleading information about FDA regulated products; promoting quick access to new medical technologies that are safe and effective; improving patient and consumer safety; responding to the new challenges

of bioterrorism and food defense, and building a stronger, science-based FDA. These goals were developed and refined in conjunction with a number of key healthcare stakeholders, and were based on important feedback from the consumer and patient communities. These are among the many critical challenges the Agency faces as it moves forward into the 21st century. I will first discuss these challenges and progress within our strategic planning effort, and then will discuss the specifics of FDA's 2005 budget request.

Efficient, Science-Based Risk Management

In FY 2005, FDA will be charged with regulating over 150,000 drugs and devices, overseeing the development of almost 3,000 investigational new drugs, monitoring 125,000 domestic product establishments including over 10,000 firms involved in the animal drugs and feed process, reviewing and acting upon an estimated 13 million import line entries, and the list goes on and on. On top of this workload, we cover the full life cycle of nearly all food and medical products, and also interact on a daily basis with all facets of Federal and State governments, consumers, public and private institutions, and foreign entities. Our proposed budget includes the equivalent of 10,844 full-time employees, including reimbursables. The numbers speak for themselves and they explain why we must practice efficient, science based risk management in fulfilling our increasingly complex mission.

FDA’s approach entails the use of the best scientific data, the development of quality standards, and the use of efficient systems and practices that provide clear and

consistent decisions and communications to the American public and the regulated industries. This is achieved by employing principles and technologies that can reduce avoidable delays and cost in product approvals, overhauling and updating the way medical products are manufactured, implementing more effective strategies for food imports and food safety, and by implementing an enforcement strategy that combines clear communications to industry backed up by effective civil and criminal enforcement, FDA will achieve quicker access to safe and effective new products, and reduce public health risks without unnecessary costs. Over the past year, our work resulted in a wealth of success stories related to enforcement, new medical product development, imports and the safety of our food supply.

Our science based enforcement strategy is one based on clarity, science, leveraging resources with our enforcement partners in Justice, Homeland Security, and the states, and most importantly, deterrence. In FY 2003, our efforts led to 341 arrests, 199 convictions, fines and restitutions of more than $800 million submitted to the U.S. Treasury (including a multimillion dollar settlement for health care fraud), 17 injunctions of firms/individuals, nearly 400 criminal cases opened, 25 seizures of violative products, and more than 500 Warning Letters. Additionally, we took action against drug counterfeiters, unscrupulous parties in the dietary supplement industry, and those who spread misinformation or commit fraud via false labeling and advertising. We remain vigilant when necessary but hold the belief that our regulations and the enforcement of the regulations should be no more burdensome than necessary.

New drug development is an extremely costly process. Today, we see cases where the cost of developing a novel drug may reach $800 million and take a decade to get from discovery to the marketplace. According to a Tufts University study, only 21.5 percent of new drugs successfully pass through the clinical phase and gain FDA approval. FDA must foster and encourage new product development by ensuring that its review and approval processes are efficient, transparent, consistent, and predictable. We need to ensure that biomedical innovation leads to the quick development of safe and effective medical products. This can be accomplished by developing quality systems for the Agency's review procedures, developing guidances in new areas of technology development, providing consumers with rapid access to generic drugs, and continuing encouragement of quality improvement in the manufacturing sector.

We want to build on the past success of industry-supported programs such as the drug review process, which is funded by a combination of appropriated dollars and user fees defined by the Prescription Drug User Fee Act that will allow FDA to collect up to $284 million in FY 2005. This program's support helped bring median approval times for standard new drug applications from 26.9 months in 1993 to 15.4 months in 2003. Increased funding for the past several years in the generic drugs program has allowed median approval times to drop from 39.7 months in 1993 to 17.3 in 2003, and an estimated time under 17 months with the FY2004 appropriation. We plan on this kind of support translating into similar success for the medical device review program with the help of budget authority and user fee dollars in FY 2004 and beyond. Increased funding

in FY 2005 will allow the Agency to expedite the speed and quality of the medical device review process.

In the past year, highlights of our medical product review process include:

- ✓ in total, approved 466 **new and generic drugs and biological products**, including 21 New Molecular Entities with active ingredients never before marketed in the U.S.;
- ✓ approved or tentatively approved a total of 373 **generic drug applications**;
- ✓ **generic approvals** included drugs for the treatment of hypertension and heart failure, the treatment and prevention of Cytomegalovirus Retinitis in AIDS and transplant patients; a treatment for major depressive disorder; and another for impetigo, an infection of the skin;
- ✓ **accelerated approvals** of a drug used for the treatment of pediatric patients with a type of myeloid leukemia — a rare, life-threatening form of cancer that accounts for approximately two percent of all leukemias in children, and another for use in combination therapy for chronic Hepatitis C;
- ✓ **over-the-counter** drug approvals including Claritin for allergies and Prilosec for frequent heartburn;
- ✓ **device approvals** included the first drug-eluting stent for angioplasty procedures to open clogged coronary arteries, clearance of the first device for diabetics which integrates a glucose meter and an insulin pump with a dose calculator into one device , and an innovative rapid HIV diagnostic test kit that provides results with 99.6 percent accuracy in as little as 20 minutes.

Lastly, FDA continues to pursue the most cost effective allocation of resources to identify food safety hazards and reduce injury and illness associated with food products. In 2003, building on an HHS strategic goal, FDA implemented new food security regulations that amount to the most substantial expansion of FDA's food safety activities in three decades. The Agency also instituted various new risk communications to improve upon more routine food safety for consumers. Additionally, the Agency continues to practice a cost effective allocation of resources through the targeting of field resources to imports that present the most significant risk. With no sign of import entries decreasing, FDA will intensify these efforts by implementing preventative food safety measures through collaborative arrangements with domestic and foreign governmental bodies.

Patient and Consumer Safety

As beneficiaries of the world's premiere heath care system, Americans should not have to endure preventable medical errors and adverse events related to medical products, dietary supplements, and foods that are responsible for thousands of deaths, millions of hospitalizations, and tens of billions in added health care costs. Americans deserve better than settling for serious health consequences that can't be spotted until many years after a product has been on the market. And Americans and their physicians deserve better than having to rely on limited and often outdated information about risks, benefits, and costs of medical treatments when they are making medical decisions - which, these days, are among the costliest and most important decisions in their lives.

So we are taking new steps to make our systems and processes for assuring the safety of food and medical products work better than ever, and to build new ways to assure better patient safety by taking advantage of modern information technology tools. We are thankful for the appropriated increases for patient, medical product safety and our various adverse event systems in the food and medical product centers that we have received in past years.

Preventing medical errors is a top priority at the Department of Health and Human Services and at FDA, and over the past year, FDA has introduced a number of solutions that are enabling a more sophisticated and effective 21st century patient safety system, thus helping lower healthcare costs and ensure longer, healthier lives for Americans. As a result of these new strategic initiatives, more programs are now in place to improve consumer safety than at any time in the Agency's history. In FY 2003, FDA issued a new proposed requirement for bar codes on nearly all prescription drugs and some over-the-counter drugs, as well as machine-readable information on blood and blood components intended for transfusion, that will result in an estimated 413,000 fewer adverse events over the next 20 years. FDA has initiated partnerships that will allow use of external medical databases to investigate specific product safety issues. We continue to encourage the development of "active" reporting systems that use fast, easy web-based reports and systems to get more extensive and timely information on new drugs, important complications, and adverse events that are not well understood. In FY 2003, we also proposed new safety standards to further reduce the incidence of adverse events, such as proposed amendments to radiation-safety standards for

diagnostic x-ray equipment and new antibiotic labeling to prevent drug-resistant bacterial strains.

Through enhanced testing and other improvements in blood safety, the risk of transmission of viruses such as HIV, hepatitis B and C has been dramatically reduced. While a blood supply with zero risk of transmitting infectious disease may not be possible, the blood supply is safer than it has ever been. The agency's Center for Biologics Evaluation and Research, worked closely with other FDA Centers, the Center for Disease Control, the National Institutes of Health, academic scientists, and the blood and diagnostic industries, in an unprecedented team effort that result in the development and implementation of investigational blood donor screening for West Nile Virus within 8 months of when the threat was first recognized. As a result, over 1,000 units of potentially WNV infected blood were identified and removed this past year before they could be transfused.

Lastly, the Agency's Center for Food Safety and Applied Nutrition launched the CFSAN Adverse Event Reporting System covering all food, dietary supplement, and cosmetic products. Consumers submitted and FDA reviewed more than 6,000 adverse events and consumer complaints in an attempt to ensure consumers are alerted quickly to any potential new dangers. Recently, the CFSAN Adverse Event Reporting System provided information on the dangers of ephedra, which has been banned by FDA.

Better Informed Consumers

So many of our stakeholders focus their attention on our mission to protect public health, and ensure the safety of the food supply and the safety and effectiveness of medical products or therapies. However, at the beginning of my testimony I restated FDA's mission which includes mention of our duty to promote public health and "[help] the public get the accurate, science-based information they need to use medicines and foods to improve their health." The public entrusts our subject matter experts and public affair specialists in Congressional districts across the country at the state and local level to provide consumers with the tools they need to make better-informed choices. These choices range from diet to medical practice recommendations to disease management on the part of the individual. Our role as an educator or informer of the public will become evermore important as patients make more independent decisions about their health and medical care. We must continue to assist the public in how to use their health care dollars as we have done with our generic drug campaigns, and at times protect them from misleading information that could endanger the public's health.

Providing information on diabetes care and prevention is a top priority of FDA and the Administration. In recent years, diabetes rates among people ages 30 to 39 rose by 70%. Research shows that good nutrition lowers people's risk for many chronic diseases, including obesity, heart disease, stroke, some types of cancer, diabetes, and osteoporosis. For at least 10 million Americans at risk for type 2 diabetes, proper nutrition along with physical activity can sharply lower their chances of getting the disease. FDA is also attempting to enhance the consumer understanding of the

relationship between diet/obesity and chronic disease. This effort is important, as currently one in three children in the U.S. is at risk of obesity. Obesity may be costing the nation as much as $75 billion or more a year. FDA must promote good nutrition by allowing consumers access to credible, science-based information, and fostering competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can promote better public health by empowering consumers to make smart, healthy choices about the foods that they buy and consume. This is a high priority for the Administration to ensure that health claims are supported by scientific information. President Bush continues to emphasize the improvement of health through better diets and lifestyles.

FDA is undertaking major new efforts to ensure consumers have the most up-to-date, truthful information on the benefits and risks of FDA regulated products. In this arena, FDA fulfills two complementary roles: ensuring that the information sponsors provide about products is accurate and allows for their safe use; and, communicating directly with the public concerning benefits and risks of products FDA regulates.

FDA's strategic plan calls for the Agency to learn how to more effectively communicate the risks and benefits of FDA regulated products to consumers, as well as those in the health and medical professions. The goal is a well-informed public, empowered to make better choices to improve their health. Just this past year, FDA has been involved in a number of consumer education campaigns related to the prudent use of antibiotics, the misuse of pain relievers, the parity between generic and name brand drugs, buying

medicines and medical products online, and several other campaigns aimed at addressing a number of areas where the consumer needs to minimize the risks and maximize the benefits of medicine use. Chairman Bonilla and Congresswoman DeLauro were instrumental in launching the "Menopause and Hormones" campaign this past September. With this Subcommittee's help, FDA teamed up with women's health organizations to raise awareness about hormone replacement therapy (HRT). The previous year, we conducted a similar campaign to raise awareness about diabetes – an issue that Congressman Nethercutt has shown great involvement with. We spread the word widely about these efforts and we almost always try to provide these messages in Spanish to reach as much of the public as possible.

Counterterrorism

FDA is improving its capability to assess and respond effectively to its mission of protecting the security of the nation's food supply, and ensuring the safety and effectiveness of medical products used to prepare and respond to biological, chemical, or radiological attacks. As Secretary Thompson reported in the July 2003 report entitled, "Ensuring the Safety and Security of the Nation's Food Supply," the Agency is working with other government agencies and the private sector to develop and implement a comprehensive strategy to protect the food supply from attack. These include additional staff for food safety field activities, greater import presence at our nation's borders, threat assessments, and additional money for food security research. FDA's medical product centers are also working harder and more creatively than ever to speed the availability of the next generation of safer, more effective countermeasures to

protect Americans against biological, chemical, nuclear, and radiological agents of terrorism.

In FY 2003, FDA implemented a number of fundamental enhancements on both the food defense and medical countermeasures fronts, in meeting the objectives of this strategic goal. In direct response to this heightened threat, and in conjunction with the Department of Health and Human Service's larger counterterrorism initiatives, FDA has implemented new steps in food defense that represent the most fundamental enhancements in the Agency's food safety activities in many years. FDA's implementation of four new food security regulations prompted by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), will be fundamental and long lasting. Two additional regulations are expected to be finalized in the near future. The Bioterrorism Act gave the Agency some potentially effective tools in identifying, preparing for or responding to terrorist attacks on the food supply. The design and implementation of these four regulations has also spawned a closer working relationship with the U.S. Customs and Border Protection Agency (CBP). Our close relationship led to a recent Memorandum of Understanding (MOU) between FDA and CBP in December 2003 that allows FDA to commission thousands of CBP officers to conduct, on FDA's behalf, investigations and examinations of imported foods in accordance with the prior notice requirements. This cooperative arrangement with FDA's sister enforcement agency was in addition to a more than six-fold increase in the number of field examinations of imported foods from FY 2001 to FY 2003 (78,000)

conducted by FDA inspectors and our state partners. Much more needs to be done in this area as we note in our Congressional budget request for an increase of $65 million.

Protecting consumers against terrorism also requires that Americans have access to safe and effective medical countermeasures. This year, FDA has worked closely with scientists and product developers and has taken new steps to speed the development of these safe, effective treatments and preventive vaccines. FDA works closely with NIH, CDC, DHHS, DoD and industry to develop new and improved treatments and vaccines to counter smallpox, anthrax, and other potential emerging biowarfare and public health threats.

FDA has had to become more proactive in identifying possible products for approval for medical countermeasures due to the fact that no known group of patients are currently affected by many of the conditions linked to biological, chemical, or radiological agents. So, in FY 2003, the Agency issued new guidance on the development of Radiogardase ("Prussian Blue") for treatment of internal contamination with thallium or radioactive cesium. Several months later, a firm submitted an application and FDA approved Radiogardase to treat people exposed to radiation contamination from harmful levels of cesium-137 or thallium after identifying existing safety and efficacy data. FDA has worked with other government agencies to facilitate the development of counter-terrorism products, such as vaccines and immune globulins against anthrax, smallpox, and botulism, by resolving regulatory issues and developing assays for potency testing. FDA also took various steps to make sure that manufacturers of medical

countermeasures are following Current Good Manufacturing Practices (CGMPs). In 2003, FDA determined that CGMP inspections were lacking for 27 manufacturers of identified medical countermeasures, and the Agency took action to address this. Even without the legislation creating Project BioShield, an act designed in part to provide incentives for developing safer, more effective countermeasures, FDA will remain the only governmental Agency involved with the approval of products necessary to prevent or treat human exposure to these terrorist agents. We hope this Subcommittee supports our $5 million request in FY 2005.

A Strong FDA

The final goal of our Strategic Plan revolves around our world-class, professional workforce that is highly dedicated and committed to making a difference. The staff is ever so aware of the need to maintain the highest level of public trust in its activities. I believe this component of our plan is the bedrock and the most critical component for the success of the Agency. For that reason, the Agency must adequately develop and support its cadre of experienced physicians, toxicologists, chemists, biologists, statisticians, mathematicians, and other highly qualified professions. Since 2001 and into the foreseeable future, we have continually sought new opportunities to improve our management, and efficiencies in our organization, infrastructure and information technology. The practice of efficient risk management certainly applies here as we must strive to adopt management practices that make the Agency's core programs most efficient. The FY 2005 request fully funds the $33.1 million ($20.6 million of which is

budget authority) to complete a part of the work force consolidation at White Oak, Maryland.

FDA's adherences to the strategies and goals of the President's Management Agenda have brought about real and positive change toward improving the management of the Agency. These five goals are Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded E-government, and Budget and Performance Integration. Over the past year, FDA management achieved a number of milestones in the area of "Strategic Management of Human Capital," including the development and phased stand-up implementation of the new shared service organization (SSO). Consolidation into the SSO, combined with improved business processes, will allow FDA to maintain administrative service levels with substantially fewer staff. Another area of continued progress is towards the goal of "improved financial performance." Due to this Subcommittee's continued support, the Agency is making progress towards the eventual replacement of its obsolete legacy accounting systems. The Department-wide Unified Financial Management System will integrate financial management to provide more timely and consistent information, and promote the consolidation of accounting operations that will substantially reduce the cost of accounting services. In addition, FDA has continued its progress towards the consolidation of its IT infrastructure by collaborating with HHS toward achieving its "One HHS" goals and objectives. FDA also competed six agency support functions in FY 2003 to determine the most efficient organization for running and managing each function. The agency determined that the in-house operations for all six functions were

the most efficient organizations for providing their respective services. We estimate savings of $16.3 million over a five year performance period from just these six organizations. These are just a few examples of FDA's outstanding progress in making efficient use out of limited resources, and practicing efficient risk management.

FY 2005 Budget Request

As I noted earlier, adequate funding of the Agency's highest priorities is vital to our success. Our FY 2005 President's budget request totals $1.845 billion, including $1.495 billion in budget authority and $350 million in user fees. The Administration proposes both increases and savings related to the President's initiatives for a net budget authority increase of $108.8 million above the FY 2004 Appropriation. Requested increases cover: Cost of Living, Food Defense, Medical Device Review, Medical Countermeasures, Bovine Spongiform Encephalopathy prevention, and the Agency's relocation of the Center for Drugs to the consolidated campus. Additionally, the budget includes management savings achieved through administrative efficiencies and savings achieved by using carryover funds from our Buildings and Facilities account. The user fee increases total more than $40 million. This proposed budget will support a total of nearly 10,800 full time employees.

Cost of Living

Adequate annual pay increases are essential to allow FDA to fully utilize programmatic increases. More than 60% of FDA's budget goes toward paying our highly skilled scientific workforce, far more than some Agencies. FDA's labor percentage is higher

due to a number of reasons, but most importantly because the Agency's diverse workload requires numerous interdependent specialists in each of the Agency's product areas, the inspectional responsibilities require great geographic diversity to perform duties across the country and around the world, and the number of personnel necessary to monitor the entire life-cycle of all products under the Agency's purview (e.g., clinical drug trials to drug application review to advertising of approved product to actual effect of drug on patient's health). The lack of cost of living increases has the potential to limit or nullify other targeted increases towards high priority Administration, Congressional and/or mission critical initiatives.

FDA is thankful for this Subcommittee's involvement in providing the Agency with additional funding to cover the cost of inflationary pay increases between FY 2002 and FY 2004. We approach you once again and request that you provide a $14.4 million increase representing a congressionally approved 4.1 percent cost of living increase for calendar year 2004 as well as a 1.5 percent increase for calendar year 2005 as proposed by the President.

Food Defense

As I noted earlier, Food Defense is a major component of FDA's strategic goal to protect America from terrorism as it relates to foods and medical products under our purview. I am also pleased to report that this Subcommittee's support in the hiring of 655 new field staff through the FY 2002 supplemental appropriation as well as the increases provided in FY 2003 is beginning to produce positive results.

During Dr. McClellan's appearance before this same Subcommittee last year, a few members expressed great concern over Secretary Thompson's statements on the vulnerabilities of the food supply. Despite some significant progress over the past year with the rapid implementation of the food registration and prior notice regulations and systems, increased training and outreach, record amounts of import examinations, expanded research programs, daily intelligence briefings of FDA officials, etc., additional steps need to be taken to fully prepare our nation to handle various types of intentional attacks on the food supply.

FDA has spent an extensive amount of time over the past year coordinating this multifaceted plan with the White House Homeland Security Council, the Department of Homeland Security, and the USDA. The result is a joint budget developed with USDA and DHS for food defense to protect the agriculture and food sectors. Based upon the Administration's current knowledge, ability to respond, and capacity to handle an actual attack, FDA requests $65 million in increased funding to shore up five key areas - $35 million for the Food Emergency Response Network [FERN], $15 million for research, $7 million for inspections, $3 million for incident management, and $5 million for biosurveillance. The investments in these particular areas will help develop awareness amongst the various components of the food sector, build upon existing surveillance tools, institute prevention techniques to shield against an attack, prepare for an attack, and provide the capacity to respond if such an event should occur.

It is also vital that the Agency has the capability to coordinate and handle a food defense response with state and local governments and other Federal agencies. We are seeking to build a food defense laboratory network among states, part of a system called FERN. FERN is comprised of labs specializing in food testing for biological, chemical and radiological threat agents and these laboratories will have the capacity to rapidly test a large number of food products. We need to make a distinction here between a corresponding network of labs handled by the Centers for Disease Control and Prevention. CDC is in charge of the Laboratory Response Network that primarily handles clinical testing of human specimens such as blood or urine.

Another system we will build upon with our FY 2005 request is the Electronic Laboratory Exchange Network or eLEXNET. This network is the nation's first seamless, integrated, secure, web-based data exchange system for food testing information. eLEXNET allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings on food products. Whereas FERN laboratories are involved in the actual analysis of food samples, eLEXNET provides a forum for the exchange of laboratory data. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Between FY 2001-2005, FDA will increase the number of import food inspections from approximately 12,000 to 97,000. Along with increased inspectional needs, FDA must take the lead in conducting or overseeing research projects that help us understand the

effects of contaminated food supplies on people. There are some hostile agents capable of entering our food supply that we don't know how they will react in humans. This is a complex challenge and we must conduct calculated risk assessments and then use limited resources to study human food consumption contaminated with these agents. Our food defense task is challenging and we will make a concerted effort to gain a greater understanding of these threats to the food supply. We currently have over 90 research projects devoted to identifying food adulteration and we hope to improve testing and identification with these projects.

Bovine Spongiform Ecephalopathy (BSE)

Although 150 deaths in Europe from variant Creutzfeldt Jacob Disease (vCJD) are linked to consumption of beef from cows with BSE, the economic impact to the farming communities was also devastating. The European Union estimated the cost of BSE contamination in affected countries to reach $107 billion and Canada's recent discovery was costing an average of $11 million a day in lost exports. The Administration is acting vigorously to limit the distribution or spread of any products suspected of carrying BSE following the December 23, 2003 discovery of a Holstein cow with BSE in the state of Washington. On January 26 of this year, FDA announced several new public health measures to strengthen the five existing firewalls that protect Americans from exposure to the agent thought to cause BSE. FDA intends to ban from human food, dietary supplements, and cosmetics a wide range of bovine-derived material so that the same safeguards that USDA implemented for meat products, also apply to food products that FDA regulates. FDA will also prohibit certain feeding and manufacturing practices

involving feed for cattle and other ruminant animals. The Agency will strengthen its current controls and implement these new protections by publishing two interim final rules.

In FY 2004, the base budget is $21.5M for BSE activities across all FDA programs. In FY 2005, we request $8.3 million for a total of $29.8 million in total funding for this initiative. With the increased funding, we will undertake a trilateral approach of increased inspections, enforcement activities, and education. The requested resources will enable the Agency to increase field BSE inspections, sample collections and analyses; increase targeted sample collections and analyses of both domestic and imported animal feed or feed components; fund 2,500 more state inspections of animal feed firms; conduct industry outreach to better inform industry of responsibilities and opportunities to prevent BSE from contaminating animal feed; and strengthen the states' infrastructures to monitor, and respond to, potential feed contamination with prohibited materials. The Administration believes that an $8.3 million request is a relatively modest increase in light of the potential health benefits and cost savings that can be achieved with these resources.

Medical Device Review

FDA is committed to ensuring that the Medical Device User Fee and Modernization Act (MDUFMA) performance goals are met and that the strongest and most effective medical device review program possible is available. The Administration requests a budget authority increase of $25.5 million for a total of $217 million, the amount needed

to match the original levels specified by law for FY 2005. On October 29, 2003, OMB Director Josh Bolten wrote to Congress describing the Administration's commitment to support this program at the level intended by MDUFMA in FY 2005 and beyond. Within the approach outlined by Mr. Bolten, the Agency is committed to meeting the original MDUFMA performance goals.

As you know, MDUFMA requires that $205.7 million be appropriated in budget authority each year for FDA's Center for Devices and Radiological Health and related field activities, adjusted for inflation (CPI). The President's FY 2005 budget meets the MDUFMA threshold for FY 2005 appropriations requirements. We look forward to working with Congress to modify MDUFMA to preclude the requirement to appropriate the entire “shortfall” from FY 2003 and FY 2004, in order to continue the user fee program beyond FY 2005. FDA is committed to achieving the performance goals of MDUFMA.

In FY 2005, FDA will utilize the appropriated increases to build upon the success in FY 2003 and FY 2004. In FY 2003, FDA invested user fee and appropriated dollars in a number of ways that will contribute to the ultimate improvement in the review process in later years, including the hiring of more than 50 new scientific, medical, engineering, and other review staff and the development of process improvements to speed review from beginning to end.

Medical Countermeasures

Counterterrorism is a major priority for the FDA and the Department of Health and Human Services. Speeding the development of safe medical countermeasures to improve protection against terrorism and emerging diseases requires that Americans have access to safe and effective medical treatments. Prior to September 11th, FDA had been engaged in coordinated efforts with other Departments to develop and make available better countermeasures for biological, chemical and radiological attacks. The urgency is far greater now and so in FY 2005, FDA will continue to work closely with scientists and product developers and take new steps to speed the development of these safe, effective treatments. FDA requests $5 million to expedite the review of new drug applications, biologics license applications, generic drugs and over-the-counter medical product countermeasures. The Agency must get involved in each facet of the process from animal studies to dosing requirements to the development of postmarket systems that will be in place to ensure rapid reaction to adverse events. These initiatives are all necessary to ensure that adequate treatments are available for a wide assortment of threats. One of these initiatives is Project Bioshield, a program designed to help ensure that medical products are reviewed and approved for safety and effectiveness in the event of war or catastrophic events. The first request for proposals for procurement of a new generation anthrax vaccine through Project Bioshield will be initiated shortly.

Center for Drugs Relocation

I can only imagine that it is difficult for members of this Subcommittee to write home about the funding you helped secure for FDA's consolidation of its Washington, D.C. metro area Headquarters Offices from 16 locations to three. However, I think they would be happy to hear that the eventual settling into the three new sites in White Oak, Laurel, and College Park, MD, create greater economies of scale and operational efficiencies. The bottom line is that you will save the American taxpayers money when this project is complete. Although substantial facility needs at White Oak are mostly addressed through the GSA appropriation, FDA must continue to seek your support for relocation costs. In accordance with the President's Management Agenda, the FDA plans to modernize document handling, use shared library and conference facilities, reduce redundancies in a wide range of administrative management tasks, convert to a single computer network, and reduce management layers. Without the requested funds, these management improvements and efficiency gains would be jeopardized.

This current plan calls for the relocation of 1,700 drug review personnel in April of 2005. The budget funds the total need for this move, $33 million, and the request includes an increase of $20.6 million in new budget authority. The remainder would come from $2.4 million in the base budget, and $10 million in PDUFA user fees. The General Services Administration has requested $89 million in their FY 2005 budget request to continue construction on the campus. If GSA's subcommittee approves the full request, the building construction would proceed as schedule. However, if GSA does not receive its full request for White Oak, it would have severe financial consequences for FDA. In a

2003 GAO report entitled "Federal Real Property: Executive and Legislative Actions Needed to Address Long-Standing and Complex Problems," the report spells out the Federal Government's problems in managing property, including the inefficient use of space. FDA would be faced with paying unnecessary rental payments for multiple properties unless the funding of construction and relocation costs are synchronized as is currently the plan.

User Fees

In FY 2005, the Agency expects to collect $350 million in user fees, primarily from PDUFA, MDUFMA, and ADUFA fee programs. These user fee programs provide substantial funding that compliment budget authority resources and allow FDA to meet agreed upon performance measures that allow for more rapid reviews of human drugs, medical devices and animal drugs. Additionally, the Agency collects modest fee amounts for the Mammography Quality Standards Act program as well as export certification and color certification programs.

President's Management Agenda & Administrative Consolidation

FDA has been very proactive in streamlining its operations and reducing its administrative expenses. Since November 2001, the Agency has worked with the Department of Health and Human Services to do its part to comply with the President's goal to improve the Strategic Management of Human Capital across the Federal Government. We have demonstrated tremendous success in efforts to delayer our organizational structure, consolidate FDA's decentralized Human Resources (HR)

services to a single FDA HR office which has consolidated into the HHS Rockville HR Center; implement a shared services organization that makes best use of administrative resources; plan for consolidated facilities at White Oak Maryland, consolidation of IT activities, and, find efficiencies via competitive sourcing or A-76 studies. Thanks to your support, we also continue to improve financial management at FDA through the planned implementation of a new financial system. In FY 2005, FDA proposes its second straight year of reductions by way of $23.1 million in savings achieved through a seven and a half percent reduction in administrative staff, or a combined reduction of fifteen percent between FY 2004 and FY 2005. In addition, no request is being made this year in the Buildings and Facilities appropriation. This represents a savings of $7 million that was devoted to higher priority programs. Approximately $4.6 million in carryover funds will sustain the program through FY2005.

Conclusion

I thank you for your commitment and continued support of FDA. I am confident that the information I provide to you today, and any additional information provided to the Subcommittee following this hearing, will give you further evidence of the Agency's needs in FY 2005, and justify the requested increases for a few selected priorities. Thank you for the opportunity to testify today. I look forward to working with all of you and your staffs in the months ahead.